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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,134	08/29/2005	Steven Jones	85084-402	3937

23529 7590 12/10/2010

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,134	JONES ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010 and 04 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,13,14,17,19-22,25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,5,13,17,19 and 20* is/are allowed.

6)☒ Claim(s) *2,14,21,22,25,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's submission filed on September 29, 2010 and October 4, 2010 has been entered. Claims 1, 2, 5, 13, 14, 17, 19-22, 25, 27 and 28 are pending and under examination. The objections to the specification is withdrawn in view of Applicant's amendment.

Oath/Declaration

2. The new oath/declaration filed October 4, 2010, is also defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The family name, residence and Post Office address of Heinz Feldman (altered, Feldman**n**) have been altered and initialed, but not dated. The residence and Post Office address can be corrected with the filing of a supplemental application data sheet. However, the naming of inventors cannot be corrected with an application data sheet (see 37 CFR 1.76(d)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 14, 21, 22, 25, 27 and 28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The embodiments of vaccines containing immunogenic fragments of the G protein of Lassa, Marburg or Ebola, methods of vaccination with the same, and methods of obtaining passive vaccines for Lassa, Marburg or Ebola viruses are not enabled by the specification.

The breadth of the claims encompasses a vaccine and method of vaccinating with a live, infectious, replication-competent recombinant VSV pseudotyped with viral hemorrhagic fever glycoprotein. The recombinant VSV does not express any VSV glycoprotein on its surface, only the VHF glycoprotein or an immunogenic fragment thereof. A vaccine or immunization is able to induce an immune response in an individual such that upon challenge, the immune system is able to neutralize the pathogen and prevent disease. The claims broadly encompass protective vaccines and methods of protecting against Lassa, Marburg and Ebola, wherein the protective antigen is an immunogenic fragment of their respective glycoproteins. Also claimed is a method of preparing a pharmaceutical composition for passive immunization. The method comprises administering the above-described VSV pseudotyped particle to a subject, harvesting antibodies from the subject and mixing the antibodies with a suitable excipient or carrier. A passive vaccine (immunization) is capable of neutralizing the invading pathogen such that disease is prevented. A passive pharmaceutical composition is also capable of inducing protection because it is being used for passive immunization.

The state of the art is that pseudotyped VSV is known to be a candidate vaccine vector. Kahn *et al*. (*J. Virology,* 2001, 75(22):11079-11087, "Kahn") discloses that foreign glycoproteins expressed in recombinant VSV can elicit specific and protective immunity in the mouse model (abstract). Kahn constructs recombinant VSV lacking the VSV G gene, contacted with cells expressing RSV F and G glycoproteins. Another construct is a recombinant VSV (lacking the G gene) that expresses RSV G and F, wherein the VSV G protein is supplied *in trans*. Kahn reviews what others have done in the art, including attenuated recombinant VSV that express influenza hemagglutinin, measles virus hemagglutinin and HIV envelope protein (see page 11080, first column, first and second paragraphs). Takada *et al*. (*J. Virology*, 2003, 77(2):1069-1074, "Takada") discloses the construction of VSV containing Ebola virus glycoprotein-encoding gene instead of the VSV G gene. Takada also discloses the administration of antibodies induced after administration of the constructs, some of which protected mice from lethal Ebola virus infection (see abstract). In general, attempts at successful passive transfer of hyperimmune animal sera have been inconsistent (see page 1069, second column, first sentence).

Mahomadzadeh *et al*. (*Nature Reviews*, 2007, 7:556-567, "Mahomadzadeh") reviews the state of the art with regard to Ebola and Marburg viruses. Included in the review are VSV constructs wherein the filovirus glycoprotein replaces the VSV glycoprotein (see Table 1). Challenge experiments with the Ebola virus glycoprotein in various constructs in mice, guinea pigs and non-human primates has shown that the glycoprotein is critical for inducing immunity (see page 563). As for passive immunity, the results show promise but are not conclusive as to the ability of antibodies alone as protective immunotherapy in humans (see pages 563-564, bridging paragraph).

The guidance provided in the specification is limited to VSV-Ebola, Lassa and Marburg constructs. Applicant's challenge experiments are solely directed to these constructs, with challenge experiments in mice and guinea pigs. Applicant provided references in the reply filed September 29, 2010 to show that these constructs (Ebola, Lassa and Marburg) are capable of protecting non-human primates against lethal challenge. However, it is important to note that the references only show construct of VSV with full glycoproteins, not immunogenic fragments of glycoproteins. Applicant has not provided guidance as to how to use immunogenic fragments that will induce protective immunity. The specification does not identify the relevant portions of the glycoproteins for each virus that are required to elicit the desired protective response.

As for passive immunity, Applicant indicates that it may be possible to use the constructs to generate serum for passive protection of humans against Ebola and other VHF agents (see page 16, second full paragraph. However, there are not examples in the literature or the specification that would lead one of skill in the art to expect that antibodies would be capable of any therapeutic effect or protective effect in non-human primates.

In view of the breadth of the claims, the state of the art, the limited guidance in the specification and limited working examples, it would require undue experimentation to make and use the vaccines as claimed.

Conclusion

4. Since claims 1, 5, 13, 17, 19 and 20 are no longer rejected as non-enabled, the Office has revisited the prior art rejection of record. Applicant's remarks and declaration of Steven Jones and Ute Stroeher filed May 19, 2010 have been fully considered and found persuasive with

regard to the unobviousness of Ito et al. (1999) in view of Kahn et al. (2001) and Vanderzanden et al. (1998) references. The obviousness rejection over the combination of these three references was withdrawn in the Office Action of July 2, 2010 in order to address enablement issues. Claims 1, 5, 13, 17, 19 and 20 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/

Primary Examiner, Art Unit 1648